REMARKS

Claims 2-7, 9-11, 16-26, 33, and 37-44 presently appear in this case. Claims 16-26 and 37 have been withdrawn from consideration. Claims 2-7, 9-11, 33 and 38 have been rejected. The official action of October 2, 2002, has now been carefully studied. Reconsideration and allowance is hereby respectfully urged.

Briefly the present invention relates to chimeric polypeptides constructed from the fusion of the naturally occurring sequences of soluble IL-6 receptor (sIL-6R) and IL-6, as well as DNA encoding same, vectors made from said DNA, and methods of making. The present invention is also related to pharmaceutical compositions containing such polypeptides and methods of use for the treatment of cancer and liver disorders, enhancement of bone marrow transplantation, and treatment of other IL-6 related conditions.

The examiner concedes that claim 2 overcomes the anticipation of the claims by Fisher. However, the examiner states that since applicants have received an action on the merits for the originally-presented invention which lacked unity of invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the examiner maintains that claims 16-26 and 37 are withdrawn from consideration as being drawn to a

non-elected invention. This restriction requirement is again respectfully traversed.

The examiner is incorrect stating that the originally-presented invention consisted only of Group I. This requirement was always traversed, and the originally-presented invention always included not only Group I but also Group II. The only issue is whether there was a special technical feature which bound those two groups. Applicants have now been able to convince the examiner that there is a special technical feature that binds the two groups. Therefore, there has not been any switch. The fact that the grounds for lack of unity has been overcome is not a reason to refuse to reconsider the lack of unity of rejection. Reconsideration and withdrawal of the restriction requirement are, therefore, again respectfully urged.

Claims 2-7, 9-11, 33 and 38 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner states that claim 38 is indefinite because it is not clear what is the amino acid sequence of the Ig-like domain and receptor pre-membrane domain of the sIL-6R so as to allow the metes and bounds of the claim to be determined. The examiner states that Ig-like domain and receptor pre-membrane domain have not been defined so as to allow their amino acid

sequence to be determined. This part of the rejection is respectfully traversed.

Claim 38 has now been amended so as to specify that the sIL-6R/IL-6 consists of the amino acid sequence which is a fusion product of the naturally-occurring sequence of sIL-6R fused to the naturally-occurring sequence of IL-6. The naturally-occurring sequences of sIL-6R and IL-6 are known and are part of SEQ ID NO:7. Changing the term "form" to "sequence" should obviate the rejection relating to the glycosylation pattern. The glycosylated chimeric molecule does not necessarily have the natural glycosylation. It is only necessary that it have the naturally-occurring sequence. Accordingly, reconsideration and withdrawal of this part of the rejection is respectfully urged.

The examiner states claim 3 is indefinite because it is not clear when the linker is "very short".

Claim 3 has now been amended to delete this term, thus obviating this part of the rejection. Reconsideration and withdrawal of the entire indefiniteness rejection are, therefore, respectfully urged.

Claims 2-7, 9-11, 33 and 38 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the chimeric sIL-6R/IL-6 chimera disclosed in SEQ ID NO:7 and the same sequence in which the

thirteen amino acid linker of SEQ ID NO:1 is substituted for the Glu-Phe-Met of residues 357-359 of SEQ ID NO:7, the examiner does not consider that the specification reasonably provides enablement for the analog language. This rejection is respectfully traversed.

Claim 38 has now been amended to specify that the sequence optionally includes a non-immunogenic linker that does not prevent the chimeric polypeptide from triggering dimerization of gp130 in human cells. Thus, claim 38(a) reads only on enabled sequences and operable linkers. Accordingly, at least new claim 39, which is directed only to paragraph (a) of claim 38, should be considered to be fully enabled and allowable. Similarly, the examiner has conceded that the constructs of claims 6 and 7 are enabled. Accordingly, it is not understood why these claims are subject to the rejection. It is respectfully urged that the examiner at least indicate that claims 6, 7 and 39 would be free of this rejection if rewritten in independent form.

With respect to the analogs of claim 38(b), the specification discloses assays to determine the triggering of the dimerization of gp130 in human cells. Thus it can be readily determined if any analog having no more than 30 changes in the 543 amino acids of SEQ ID NO:7 maintain the required function. It is well within the skill of the art to

make random changes in the two domains and then test in the given assay whether it maintains the function. The analogs maintain at least 94% identity to the base sequence. This is a reasonable degree of breadth. Since each such analog can readily be tested without undue experimentation, applicants are entitled to this degree of breadth and the disclosure is enabling. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore earnestly solicited.

Respectfully submitted,

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